

Gloria Brienza
Page 2

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Date Sent: June 27, 2002

Attorney Name: Bonnie Weiss McLeod

Client Name: Carnegie Institution of Washington

Number Pages Transmitted: 12
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JOB #743

DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	STATUS
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FAX MESSAGE

Send To:

Name:	Susan Dymecki	FAX Number:	(617) 432-4811
Firm:	Harvard Medical School- Department of Genetics	Telephone Number:	(617) 432-4812
Name:	Gloria Brienza	FAX Number:	(202) 387-8092
Firm:	Carnegie Institution of Washington	Telephone Number:	(202) 939-1104

From:

Name **Bonnie Weiss McLeod** Floor: **3rd** Operator Sending:
Telephone Number: **202-739-6150** Time Sent: Date Sent: **Sept. 16, 2002**
Number of Pages (INCLUDING COVER PAGE): **5**

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Comments:

Re: U.S. Patent Appln. 08/866,279
Inventor(s): DYMECKI *et al.*
Entitled: USE OF FLP RECOMBINASE IN MICE
Former Ref. No.: 020263-0234805
New Ref. No.: 056100-5020

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JOB #731

	DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	STATUS
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New Ref. No.: 056100-5020

01-WA/1759523.2

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001 3:40 6100507016171374811- - - - - S 00:00 000 N A

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C O U N S E L O R S A T L A W

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March 20, 2003

VIA FACSIMILE and U.S. MAIL

CONFIDENTIAL COMMUNICATION

Dr. Susan M. Dymecki
Harvard Medical School
Department of Genetics
200 Longwood Avenue
Boston, MA 02115

Re: U.S. Patent Application No.: 08/866,279
Inventors: Susan M. DYMECKI, et al.
Final Office Action
Due Date: May 25, 2003
Final Due Date: August 25, 2003
Title: USE OF FLP RECOMBINASE IN MICE
Our Reference: 056100-5020-01

Dear Susan:

Enclosed is a copy of a **Final Office Action** dated **February 25, 2003**, which we received from Pillsbury Winthrop on **March 10, 2003**. We will request a change of correspondence address when we file the next paper. A response to the outstanding Office Action is due on **May 25, 2003**. The period for response may be extended to expire on **August 25, 2003**. No references were received with the Office Action.

At the outset, we are pleased to report that claim 1 has been declared allowable. Although the Examiner did not make this indication on the front page of the Action, she states that claim 1 is allowable in her concluding remarks (see page 5 of Action).

We are still puzzled how claim 1 can be allowable where narrower claims that are dependent on claim 1 and encompassed within the scope of claim 1 for enablement have been rejected. This is highly unusual but might occur where a narrower claim sets forth an inoperative embodiment. This seems to be the Examiner's justification for maintaining the rejection as to all the dependent claims (see the bottom of claim 3), however the Examiner has not provided any evidence or argument as to why every dependent claim would be inoperative.

Claim 51 remains rejected for the phrase "growth/differentiation factors," however, it appears that this rejection would be resolved by separating the words "growth" and "differentiation." We can attend to this amendment without instruction.

CONFIDENTIAL COMMUNICATION

Dr. Susan M. Dymecki
March 20, 2003
Page 2

Claim 52 was rejected under § 112, second paragraph due to an inadvertent spelling error, and claim 59 was rejected for not including the phrase "FLP recombinase transgene" in step (c). We can attend to these amendments without instruction. Resolution of these minor rejections of claims 52 and 59 would render these claims allowable, since these claims were not included in the enablement rejection. However, as with all the other dependent claims, the claims that are dependent on claims 52 and 59 were rejected for lack of enablement.

In response to the Office Action, we recommend correcting the minor § 112, second paragraph issues, and making one last attempt to convince the Examiner that the enablement rejection of the dependent claims is improper. As an example, claim 62 is dependent on claim 59 and merely recites several marker genes that are known and commonly used in the art. There would be no reason to expect that the use of any of these particular marker genes would render the method of claim 59 inoperable, and the Examiner has provided no evidence to suggest otherwise. The danger in making further arguments, however, is that the Examiner may change her mind as to the allowability of the broad claims. On the other hand, if we were to cancel the dependent claims, a potential infringer might argue that the allowed claims are limited to only what is exemplified in this specification.

As a final matter, please also find enclosed the Notice of Publication for the above-referenced patent application, which includes the patent publication number and publication date. Publication of this application may give rise to certain provisional rights relating to damages for infringement under 35 U.S.C. § 154(d) if actual notice is given. The U.S. Patent and Trademark Office does not supply a copy of the publication with the Notice of Publication. You can download the publication from the USPTO website (<http://www.uspto.gov/patft/index.html>). If you have any questions regarding the Notice of Publication or provisional rights, please do not hesitate to contact us.

We look forward to receiving your instructions regarding the Office Action.

Sincerely,



Bonnie Weiss McLeod

BWM:djs/vwf
Enclosures

cc: Gloria Brienza (w/ enclosures)
Paul Kokulis (w/out enclosures)



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Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/866,279	05/30/1997	SUSAN M. DYMECKI	234805

CONFIRMATION NO. 9567

CUSHMAN DARBY & CUSHMAN
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WASHINGTON, DC 200053918



OC000000009105160

DEC 13 2002

Title: USE OF FLP RECOMBINASE IN MICE

Publication No. US-2002-0170076-A1

Publication Date: 11/14/2002

MORGAN, LEWIS & BOCKUS LLP

Date Mailed: 11/14/2002

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Crystal Gateway 4, Room 335, Washington, D.C. 20231, or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at (703) 305-3028.

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56100-5020-01

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/866,279	05/30/1997	SUSAN M. DYMECKI	234805	9567

7590 02/25/2003
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1100 NEW YORK AVE N W NINTH FLOOR
WASHINGTON, DC 200053918

EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/25/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

MAR 10 2003

MORGAN, LEWIS & BOCKUS LLP

Doctested 3/12/03 Attorney PNK/BWM
Case 5600-5020-01
Due Date 5/25/03
Action Final OA / NOTICE OF APPEAL
By [Signature] Chk SDW

Office Action Summary	Application No. 08/866,279	Applicant(s) DYMECKI, SUSAN M.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 50-52, 55-59 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-21, 50-52, 55-59, and 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The response filed December 4, 2002 (Paper No. 35) has been entered. Claims 1, 20, 51, 52, 55-57, 59, and 62-64 have been amended. Claims 22-49, 53, 54, 60, and 61 have been cancelled.

Accordingly, Claims 1-21, 50-52, 55-59, and 62-65 remain pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 2-51, 55-58, and 62-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising an FLP recombinase transgene under the control of a tissue-specific promoter and a reporter gene under the control of a non-tissue-specific (ubiquitous) promoter, wherein the reporter gene comprises a disruption comprising two FLP-recognition sequences in direct repeat orientation, such that the reporter gene produces active product only when in the recombined form, does not reasonably provide enablement for transgenic mice having the wide variety of different combinations of FLP-recognition sequences and transgenes, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The specification fails to provide an enabling disclosure for the full scope of the claims because the phenotype of a transgenic mouse is unpredictable for reasons of record advanced on pages 2-6 of the Office Action of Paper No. 22 (mailed 10/25/00), on pages 2-8 of Paper No. 26 (mailed 7/18/01), and on pages 2-3 of the Office Action of Paper No. 33 (mailed 6/5/02). Thus, the specification fails to teach how to use the full scope of the claimed transgenic mice. In the absence of disclosure of a transgene-dependent phenotypic alteration, one skilled in the art would not know how to use the claimed transgenic mice over the full scope. Thus, one skilled in the art would have been required to engage in undue experimentation in order to make and use the claimed transgenic mice over the full scope.

The claims must be congruent with the asserted utility of the invention, which in the instant case is cell fate mapping. The instant claims are not congruent with the asserted utility of cell fate mapping. In the interview of March 29, 2001, the inventor provided convincing arguments for the utility of cell fate mapping. The Examiner evaluated enablement for this utility with respect to the application as-filed and identified a scope of enablement consistent with this utility, the only asserted utility for which a scope of enablement exists. However, the claims remain broader than the scope of enablement.

At page 7, paragraph 3 of the response, Applicants question the reasoning behind the separate rejection of Claim 2-60 and 62-65 and Claim 1. Applicants should note that the scope of enablement for Claim 1 is different from the scope of enablement for Claims 2-60 and 62-65.

At page 7, paragraph 3 of the response, Applicants assert that the amendment to Claim 1 should resolve the rejection as it pertains to Claims 2-21 and 50-51 since these claims depend from Claim 1 and are more narrow in scope than Claim 1. However, as clearly indicated in the rejection, the scope of enablement for Claims 2-21 and 50-51 is different from the scope of enablement for Claim 1. Furthermore, the suggestion that claims that are more narrow than an enabled claim automatically makes them enabled is incorrect, as a broad claim is permitted to cover a vast number of inoperative embodiments.

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At page 7, paragraph 3 of the response, Applicants assert that the specification is not limited to the utility of cell fate mapping, as it also discusses making mutations in specific cells and site specific integration of transgenes. Applicants offer no further arguments with regard to **enablement** for these utilities. Further, it is noted that enablement for these utilities has been fully evaluated in great detail in the Office Actions of Paper Nos. 22 (mailed 10/25/00), 26 (mailed 7/18/01), 30 (mailed 2/11/02), and 33 (mailed 6/5/02).

New Matter

With regard to the new matter rejection regarding the term "ubiquitous promoter" (applied to Claims 54 and 61, now cancelled), the Examiner accepts the passage on pages 16-17 of the specification to which Applicants refer as implicit support for the term "ubiquitous promoter." Although the passage does not provide literal support for the term, the passage refers to "regulatory regions for ubiquitous expression." At page 16, paragraph 2, the passage refers to a number of "regulatory regions" including promoters. Amended Claims 52 and 59 and the claims which depend from them, now recite a "ubiquitous promoter."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 51 stands and Claims 52, 55-57, 59, and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 remains indefinite in its recitation of "growth/differentiation factors and their receptors" because the metes and bounds are not clearly set forth. The specification does not offer a definition of this term that would serve to define the metes and bounds.

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At page 10, paragraphs 1 and 3 of the response, Applicants argue that gene products constituting growth or differentiation factors and their receptors were well known at the time the application was filed and would be immediately recognized by a person of skill in the art. At paragraph 3, Applicants refer to a variety of "growth factors." At page 11, paragraph 2 of the response, Applicants refer to a variety of "differentiation factors." However, the claim language does not recite "growth factors" or "differentiation factors" but rather recites "growth/differentiation factors." The metes and bounds of this term are not clearly set forth and the specification does not offer a definition of this term. Providing a definition for the term "differentiation" does not serve to elucidate the definition of the term "growth/differentiation factors."

Claim 52 and 55-57 are indefinite in their use of the term "intergrated" because this appears to be a typographical error. Claim 52 as pending prior to this amendment used the correct spelling "integrated." See the amendment of Paper No. 32, submitted March 18, 2002. This rejection is necessitated by Applicants amendment.

Claims 59 and 62-65 are indefinite in their recitation of "said Flp transgene" in step (c) because the term lacks antecedent basis. The claim has been amended in steps (a) and (b) to recite an "Flp recombinase transgene." This rejection is necessitated by Applicants amendment.

Conclusion

Claim 1 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing

Art Unit: 1632

date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER